

REMARKS

Claim Status

Claims 1, 3, 5-7, 9-12 and 49-53 are pending in the present application. No additional claims fee is believed to be due.

Claims 2, 4, 8, 13-48 and 54-78 were previously cancelled without prejudice.

Claims 49-53 were previously withdrawn.

Claims 1 and 49 have been amended because to correct the formalities. Support for the amendment is found at page 25, lines 9-10 of the specification.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Claim Objection

Claim 1 has been objected to because it did not follow the proper formalities because the examiner states that the abbreviation HIPE should be given its full name or with the full name in parenthesis when it is first used. Claim 1 has been amended. Withdraw of the objection is respectfully requested.

Rejection Under 35 USC §103(a) Over de Smidt et al. (US 6,703,369) in View of Maeder et al. (US 6,703,319) and Park et al. (US 5,750,585)

Claims 1, 3, 5-7, and 9-12 are rejected under 35 USC §103(a) as being unpatentable over US Patent 6,703,369 to de Smidt et al. in view of US Patent No. 6,730,319 to Maeder et al. and US Patent No. 5,750,585 to Park et al.

The Applicants respectfully traverse the rejections. The Examiner has not met the burden of establishing a *prima facie* case of obviousness. See MPEP § 2143.01. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

The Examiner states that de Smidt et al., teaches a pharmaceutical composition comprising a glyceride ester or a fatty acid, with a melting point of 37 °C, and a lipase

inhibitor. Neither de Smidt et al., Maeder et al., nor Park et al. teach or suggest the stiffening agents as recited in Claim 1. De Smidt et al. discloses only compositions including lipase inhibitors in combination with fatty acid esters of polyols as a second component. See Column 2, lines 43-50. The current application claims and discloses ethers of fatty alcohols mono-functional alcohols (R-OR'), and not polyols. De Smidt et al. does not even mention or consider anything other than polyols. Maeder teaches only fatty acids and fatty acid salts, particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor. See Column 3, starting at line 12. Additionally, Maeder et al. does not teach a ratio of stiffening agent to lipase inhibitor, by weight, from at least 5:1.

The present invention is directed to a composition useful for stiffening unabsorbed dietary fat and through such stiffening the viscosity of the substance in vivo resulting in the formation of solids, semisolids, pastes, and gels. See present specification page 8, lines 3-6 (emphasis added). The Examiner states that Maeder et al. teaches a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point $>$ and or $=$ to 37°C wherein the fatty acid is selected from behenic acid. Maeder et al. discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form. See Column 3, lines 42-46. Applicants respectfully submit that it is error to find an invention obvious where prior art references diverges from the invention at hand. *W.L. Gore & Assocs. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983). In determining obviousness, "[t]he claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and the obviousness of making the combination." *Lindeman Maschinenfabrick GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984); *Maize*, 5 USPQ 1788, 1793 (Fed. Cir. 1988). "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02. The Maeder et al. reference discloses the pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form. See Column 3, lines 42-46. One of ordinary skill in the art would have no motivation to select the use of a pharmaceutical composition that provides exactly the opposite effect i.e. solid to liquid that the current invention sought to reverse i.e. liquid to

non-liquid with the present invention. Applicants respectfully submit that if proposed modification would render the prior invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01 citing *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The Examiner concedes that de Smidt et al. and Maeder et al. fail to teach a non-digestible, non-absorbable, open-celled HIPE foam. The Examiner states that Park et al. teaches a non-digestible, non-absorbable, open-celled high internal phase emulsion (HIPE) foam compositions and methods of orally administering said forms compositions for the treatment of obesity. Park et al. discloses hydrogels which are described at column 3 to column 4, starting at line 50 of column 3. However, the hydrogels of Park et al. are prepared by introducing a gas into a monomer solution comprising at least one *hydrophilic* olefin monomer compound. The hydrogels of Park et al. are not formed from an emulsification process using hydrophobic monomers. The compositions of Park et al. are formed by introducing gas into a hydrophilic olefin monomer solution during polymerization of the monomer. Thus, the compositions of Park et al. and the present invention are not the same. In addition, the only mention of treatment of gastric conditions by Park et al. is as a physical barrier due to the large swelled size of the hydrogels of Park et al. such that the large swelled hydrogel reduces the amount of physical space in the stomach. There is nothing in Park et al. that teaches or suggests that the hydrogels would sequester one or more lipophilic materials. Additionally, if one were to consider Park et al., does not teach or suggest the stiffening agent of the current invention.

Even assuming *arguendo* that one were to combine de Smidt et al., Maeder et al., and Park et al. one would still fall short of the Applicants' claimed invention only to arrive at a compositions that includes lipase inhibitors in combination with fatty acid esters of polyols, and a hydrogel that swells to form a physical barrier that reduces the amount of physical space in the stomach, and the composition is able to transform the active ingredient after oral ingestion from a solid to a liquid form. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

CONCLUSION

This Response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented, reconsideration of this application and allowance of the pending claims are respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By /Cynthia L. Clay/

Cynthia L. Clay

Registration No. 54,930

(513) 983-9764

Date: August 23, 2010
Customer No. 27752